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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,470	DE REUSE ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,8-12,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *6,8-12,25-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 6, 8-12 and 25-26 are pending.
Claims 1-5, 7,13-24 and 27-28 have been canceled.
Claims 8-12 have been amended to no longer depend from claim 7, and amended to depend from independent claim 6.
1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejections Withdrawn

1. The first sentence of the Specification has been amended to correctly set forth Applicant's claim to priority.
2. The Drawings are not longer objected to as they now refer to both frames 3A and 3B.
3. Prior art rejection applied against claims that have been canceled are herein withdrawn.
4. Claim 6 rejected under 35 U.S.C. 102(a) as being anticipated by WO97/26908, in light of Applicant's traversal.
5. Claim 6 rejected under 35 U.S.C. 102(b) as being anticipated by Zopf (US Pat. 5,514,660), in light of Applicant's traversal.

Rejections Maintained

6. Claims 6, 9-11, 25-26 rejected under 35 U.S.C. 102(e) as being anticipated by Labigne et al, for reasons of record in paper number 4202004, paragraph 5.
7. Claims 6, 12 rejected under 35 U.S.C. 102(e) as being anticipated by Iverson et al (US Pat. 6,124,271), for reasons of record in paper number 4202004, paragraph 6.
8. Claims 6, 8-11,25-26 rejected under 35 U.S.C. 102(b) as being anticipated by Nakazawa et al (US Pat. 5,214,053), for reasons of record in paper number 4202004, paragraphs 7-8.
9. Claims 6,8-11 rejected under 35 U.S.C. 102(b) as being anticipated by Hartmann (US Pat. 5,900,410), for reasons of record in paper number 4202004, paragraph 9.

Response to Arguments

1. Applicant's arguments filed July 23, 2004 have been fully considered but they are not persuasive.

10. The rejection of claims 6, 9-11, 25-26 under 35 U.S.C. 102(e) as being anticipated by Labigne et al, is traversed on the grounds that:

a. Labigne et al does not teach each and every element of Applicant's present invention as claimed.

11. It is the position of the examiner that the claimed method must administer a molecule that is "capable of inhibiting the growth or survival of H.pylori in vivo". Clearly a composition that comprises the UreI molecule, or anti-UreI antibodies is capable of treating or preventing H.pylori infection.

b. Traversal directed to process steps used to define functional capability of the "molecule" administered sets forth a combination of claim limitations for a molecule defined by product by process limitations. A molecule that has the same or equivalent capabilities obtained by a different process can be administered to a human or animal, and must evidence the functional capability required by the claim: "inhibiting the growth or survival of H.pylori in vivo". A molecule with the recited capability and is administered to a human or animal meets the positively recited methods step of independent claim 6.

c. The phrase "wherein the identification" lacks antecedent basis in claim 1 which only positively recites the methods step of "administering", therefore the combination of claim limitations following the phrase "the identification" defines product by process steps used to define one means of obtaining the functional capability of the molecule administered. A product identified and administered with the same or equivalent capability obtained by a different process would meet the recited functional characteristic of inhibiting growth or survival of H. pylori in vivo.

12. In light of the fact that Labigne et al disclose compositions of Helicobacter pylori UreI protein, and antibodies to UreI (col. 10, lines 6-8, 19-20) which are capable of inhibiting (col. 11, lines 27-32) the growth or survival of H. pylori in vivo (see col. 10, lines 21-28), and teach a method of treating H. pylori infection through administering these compositions to a human or animal (see col. 9, lines 31-35; see col. 9, line 33; lines 38-39), Labigne et al still anticipates the instantly claimed invention. No evidence has been provided to show that the molecules of Nakazawa et al do not evidence the recited capability of inhibiting growth or survival of H.pylori in vivo. The rejection made of record in maintained.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

13. The rejection of claims 6, 12 under 35 U.S.C. 102(e) as being anticipated by Iverson et al (US Pat. 6,124,271), is traversed on the grounds that:

Claim 6 recites "treating or preventing H.pylori infection with a molecule displaying a differential effect on parental and UreI deficient strains" and Iversen et al does not show a differential effect.

14. It is the position of the examiner that claim 6 administers a molecule that must evidence the capability of inhibiting growth or survival of H.pylori in vivo. The molecule can be defined

by the recited process steps, but the phrase "the identification" lacks antecedent basis in the claim and are therefore is viewed to be a combination of claim limitations that defines product by process limitations for a molecule with the recited capability.

15. The molecule administered must be "capable of inhibiting the growth or survival of H.pylori in vivo" in order to meet the positively recited administering methods step. The molecule administered by Iverson et al is an antisense oligomer with the recited capability, specifically a molecule that will inhibit H. pylori urease expression and is claimed by Iverson et al as being capable of treating H.pylori infection. Through inhibiting transcription and translation of the urease coding sequence, growth or survival of H.pylori in vivo would be inhibited (see Iverson et al, col. 2-22, claims 1-15) because one of the pathogens key mechanisms for survival in vivo (the stomach) is inactivated. No evidence has been provided to show that the molecules of Nakazawa et al do not evidence the recited capability of inhibiting growth or survival of H.pylori in vivo. Iverson et al anticipate the instantly claimed invention as now claimed.

16. The rejection of claims 6, 8-11,25-26 under 35 U.S.C. 102(b) as being anticipated by Nakazawa et al (US Pat. 5,214,053), is traversed on the grounds that:

c. The administered molecule must evidence a differential effect on parental and Ure I deficient strains.

17. It is the position of the examiner that the process steps used to define the capability of the administered molecule may be determined through a different process, as long as the administered molecule evidences the required capability of inhibiting growth and survival of

H.pylori in vivo and must serve to treat or prevent infection. The rejection is maintained for reasons of record. No evidence has been provided to show that the molecules of Nakazawa et al do not evidence the recited capability of inhibiting growth or survival of H.pylori in vivo.

18. The rejection of claims 6, and 8-11 under 35 U.S.C. 102(b) as being anticipated by Hartmann (US Pat. 5,900,410), is traversed on the grounds that:

a. The administered molecule must evidence a differential effect on parental and Ure I deficient strains.

19. It is the position of the examiner that the process steps used to define the capability of the administered molecule may be determined through a different process, as long as the administered molecule evidences the required capability of inhibiting growth and survival of H.pylori in vivo and must serve to treat or prevent infection. No evidence has been provided to show that the molecules of Hartmann do not evidence the recited capability of inhibiting growth or survival of H.pylori in vivo. Hartmann claims a method of treating H.pylori infection with the claimed compositions; this is the reference applied against the claims. Nawaz et al is not used in the rejection as an applied reference, but only provides evidence for how Mg cations function in relation to aliphatic amidase. The instant claims do not require complete inhibition of UreI, an aliphatic amidase, but allows for partial inhibition of UreI, through the recitation of a relative term that include partial and complete inhibition of H.pylori growth or survival. The instantly claimed method is directed to a genus of methods for treating H.pylori infection, which includes both partial or complete inhibition of growth or survival. Hartmann administers a composition that has the capability of inhibiting growth or survival of H.pylori infection in vivo,

and Hartmann concluded that divalent cations should be included in the claimed compositions and methods of Hartmann. The functionality of the cations relative to aliphatic amidases was provided in light of the Nawaz et al reference, and the Nawaz et al reference has nothing to do with what components Hartmann decided to include in the claimed compositions and methods used to treat H.pylori infection of US Pat. 5,900,410). Hartmann anticipates the instantly claimed invention.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
October 28, 2004

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